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No. 06-1249

In the
Supreme Court of the United States

WYETH,

Petitioner,

v.

DIANA LEVINE,

Respondent.

On Writ of Certiorari to the Supreme Court of Vermont

BRIEF OF TORTS PROFESSORS MARK P. GERGEN AND MICHAEL D. GREEN AS *AMICI CURIAE* IN SUPPORT OF RESPONDENT

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INTEREST OF THE *AMICI CURIAE*[1]

Amici are law professors who regularly teach and write about the law of torts. Each has taught for more than 20 years, has written extensively in the field, and has been a reporter for a segment of the *Restatement (Third) of Torts*. Further biographical information is included in the Appendix.

Amici have no stake in the outcome of this case other than their academic interest in the logical and rational development of the law. Because this case implicates fundamental issues of tort law, *amici* believe that their unique perspective may assist the Court in its resolution of this case.

SUMMARY OF THE ARGUMENT

Petitioner's policy arguments for preemption are unduly optimistic about the ability of the Food and Drug Administration ("FDA") to protect the public from unreasonably dangerous drugs. The civil system complements FDA regulation of drugs. Even if the agency were adequately funded and staffed, and even if drug makers always cooperated with the agency to ensure the safety and efficacy of drugs, tort liability would still be necessary to encourage drug makers to provide adequate warnings about risks that are outside the agency's purview when it approves a drug and labeling. Tort liability also serves compensation and corrective justice interests that FDA regulation was never intended to serve.

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[1] No counsel for a party authored this brief in whole or in part and no person other than *amici* and their counsel made a monetary contribution to fund its preparation or submission. The parties have consented to the filing of this brief.

Petitioner's policy arguments for preemption also assume an unduly pessimistic view of the civil justice system. Mechanisms already exist within the civil justice system to ensure courts and juries defer to FDA approval of drugs and labeling and to protect drug makers from spurious claims. State courts have struck a balance by adopting rules that shield a drug maker from design-defect claims while holding a drug maker liable if it fails to give adequate warning of a drug's risks. This facilitates getting new FDA-approved drugs on the market while using failure-to-warn liability to encourage dissemination of risk information and so enable health-care professionals and the public to make informed decisions about drugs. Other rules address specific arguments for preemption. Rules of evidence enable courts to screen out claims that lack a sound scientific basis. The hypothetical danger of drug makers' inundating the public with warnings to avoid liability is dealt with by the learned intermediary doctrine, which provides that a drug maker can satisfy the duty to warn by providing information to health-care professionals.

The American Law Institute ("ALI"), state courts, and state legislatures have directly grappled with the arguments for and against requiring courts and juries to defer to FDA approval of a drug's labeling in developing what has come to be called the defense of regulatory compliance. Many states have statutes that require courts and juries to give some deference to FDA approval of a drug's labeling. While it remains a minority position, there is some support for a rule that would shield a drug maker from liability for failure to warn if the FDA addressed the specific risk at issue in a case and determined additional

warning was unwarranted. These rules would not shield petitioner here because the FDA never approved the administration of Phenergan by IV-push. No court and only one state legislature, Michigan, has gone so far as to make FDA approval of a drug and its labeling a shield against claims involving risks that the FDA has not addressed.

This experience teaches that preemption is not an either-or proposition. A narrow rule of preemption is similar to a strong form of the common-law defense of regulatory compliance. This would treat FDA approval of the adequacy of a warning with regards to a specific risk as determinative of the issue of the reasonableness of the warning about this risk so long as the FDA considered all relevant information. Petitioner would not be satisfied with such a rule for it would not shield it from liability in this case. A broad rule would make the FDA solely responsible for ensuring the adequacy of warnings of FDA-approved drugs by precluding all failure-to-warn claims with respect to FDA-approved drugs. This would shield a drug maker from liability even if it withheld relevant risk information from the FDA or otherwise failed to cooperate, and even with respect to risks that appear post-marketing or that involve "off-label" uses, which the FDA has not had an opportunity to consider. This would be a radical change from the status quo. Only Michigan has gone this far. This Court should leave it to Congress to tailor an appropriate preemption rule and to decide whether the rule should apply retroactively or only prospectively.

ARGUMENT

I. Preemption of state-law tort claims based on FDA regulation of a drug is unwarranted because the civil justice system complements the FDA's regulation of drugs.

The civil justice system complements FDA regulation of drugs on two general dimensions. First, tort liability serves several important functions that FDA regulation of drugs was never intended to serve. Most of these functions involve compensating people who are injured, usually because a drug maker failed to provide adequate warning of a drug's risks. Whether the civil justice system should be preempted from serving these compensatory functions raises fundamental questions of morality and policy. Tort liability also complements the FDA's regulatory function. Whether the civil justice system should be preempted from serving this function turns on an assessment of the relative strengths and weaknesses of FDA regulation and of civil liability as mechanisms for protecting people from unreasonably dangerous drugs. At bottom, the answers to both questions turn on whether we as a society choose to err on the side of over- or under-protecting the public from unreasonably dangerous drugs. To date, state courts have struck a balance by eliminating barriers that might deter the introduction of new drugs, relying on the FDA to keep unreasonably dangerous drugs off the market, while imposing failure-to-warn liability to encourage dissemination of risk information and so enable health-care professionals and the public to make informed judgments about drugs.

Until the FDA's recent change in position, no official body, not even the agency, had concluded that

a general rule preempting failure-to-warn liability was needed to enable the agency to accomplish its mission.[2] The FDA announced a change in its views on the need for preemption in the preamble to the 2006 labeling regulations. Putting aside the question whether this was an appropriate way to make such an important change in policy, it is striking that this case is not within any of the categories of cases for which the agency itself deemed preemption to be necessary.[3]

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[2] There is explicit recognition of this in the 2000 proposed regulations on prescription drug labeling. The preamble stated: "FDA has determined that this proposed rule does not contain policies that have federalism implications or that preempt State law." 65 FED. REG. 81,082, 81,103 (Dec. 22, 2000).

[3] The preamble to the 2006 labeling regulations states, in pertinent part:

> FDA believes that at least the following claims would be preempted by its regulation of prescription drug labeling: (1) Claims that a drug sponsor breached an obligation to warn by failing to put in Highlights or otherwise emphasize any information the substance of which appears anywhere in the labeling; (2) claims that a drug sponsor breached an obligation to warn by failing to include in an advertisement any information the substance of which appears anywhere in the labeling, in those cases where a drug's sponsor has used Highlights consistently with FDA draft guidance regarding the "brief summary" in direct-to-consumer advertising . . . ; (3) claims that a sponsor breached an obligation to warn by failing to include contraindications or warnings that are not supported by evidence that meets the standards set forth in this rule, including § 201.57(c)(5) (requiring that contraindications reflect "[k]nown hazards and not theoretical possibilities") and (c)(7); (4) claims that a drug sponsor breached an obligation to warn by failing to include a statement

A. Compensation and loss spreading.

By compensating individuals harmed by drugs, tort law serves some ends that FDA regulation simply is not meant to serve. Most importantly, "preemption completely eliminates the corrective justice role that common law courts have played in this country since its founding." THOMAS O. MCGARITY, THE PREEMPTION WAR 33 (Yale 2008). For much of this country's history, the purpose of tort law was thought to be redressing moral wrongs, not regulation or deterrence. In the last half century in the United States, tort law has come to be understood as also serving a regulatory function. But corrective justice or compensation remains an important goal.

> in labeling or in advertising, the substance of which had been proposed to FDA for inclusion in labeling, if that statement was not required by FDA at the time plaintiff claims the sponsor had an obligation to warn (unless FDA has made a finding that the sponsor withheld material information relating to the proposed warning before plaintiff claims the sponsor had the obligation to warn); (5) claims that a drug sponsor breached an obligation to warn by failing to include in labeling or in advertising a statement the substance of which FDA has prohibited in labeling or advertising; and (6) claims that a drug's sponsor breached an obligation to plaintiff by making statements that FDA approved for inclusion in the drug's label (unless FDA has made a finding that the sponsor withheld material information relating to the statement).

71 FED. REG. 3922, 3935-36 (Jan. 24, 2006) (second alteration in original). The closest categories are (3), (4), and (5). The case is not within (3) because the risk of intravenous injection of Phenergan is well-established. It is not within (4) because a warning against administration of Phenergan by IV-push was never proposed to the FDA. It is not within (5) because the FDA never prohibited Wyeth from warning against administration of Phenergan by IV-push.

See *Warriner v. Stanton*, 475 F.3d 497, 501 (3d Cir. 2007) (reaffirming that New Jersey's tort policies consist primarily of compensation and deterrence); *Hannah v. Heeter*, 584 S.E.2d 560, 566 (W. Va. 2003) ("the three fundamentals of tort law are morality, compensation, and deterrence") (internal quotation marks omitted). See generally Gary T. Schwartz, *Mixed Theories of Tort Law: Affirming Both Deterrence and Corrective Justice*, 75 TEX. L. REV. 1801 (1997). In Europe, civil liability generally still is understood to serve corrective justice. For this reason, there has been almost no movement in Europe to eliminate civil liability for unreasonably dangerous products and to rely solely on administrative regulation of dangerous products.[4]

From the perspective of corrective justice, FDA approval of drug labeling is relevant only insofar as

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[4] In the European Union ("EU") there generally are two tiers of administrative approval, at the EU level and the member state level. The European Agency for the Evaluation of Medicinal Products ("EMEA"), which was established in 1995, must authorize marketing a drug within the EU. Most individual countries also require approval by their own agency, such as the Medicines and Healthcare Products Regulatory Agency ("MHRA") in the UK and the Federal Institute for Drugs and Medical Devices ("BfArM") in Germany. See CHRISTOPHER HODGES, EUROPEAN REGULATION OF CONSUMER PRODUCT SAFETY, Ch. 4 (Oxford 2004). An industry position paper has cited "a very low level of compensation claims" as evidence of the success of the administrative system. *Id.* at 43.

Section 4(1)(a) of the 1985 European Directive on Product Liability makes compliance with a regulation a defense. See SIMON WHITTAKER, LIABILITY FOR PRODUCTS 522 (Oxford 2005) ("This defence is not, of course, a defence of compliance with public standards (though such a defence has been suggested): it requires that the defect itself results from the regulatory standard.").

it establishes that a company did nothing morally blameworthy in not providing an additional warning. FDA approval of a label would be significant on this question if the FDA advised a drug maker that a particular warning was adequate with regards to the specific risk in question in a case (and it would be decisive if the FDA forbade the drug maker from providing an additional warning), but otherwise it is of no obvious relevance.

Compensation through strict liability also serves to spread losses. See, e.g., *New Texas Auto Auction Servs., LP v. Gomez De Hernandez*, 249 S.W.3d 400, 404 (Tex. 2008) (stating the justifications for strict liability are "(1) compensating injured consumers, (2) spreading potential losses, and (3) deterring future injuries"); *Antone v. Greater Arizona Auto Auction*, 155 P.3d 1074, 1076 (Ariz. Ct. App. 2007) ("[T]he underlying justification for imposing strict liability is risk/cost spreading to those parties in the distribution chain that are best able to both bear the cost and protect the consumer from defective products."), *review denied* (Ariz. Sept. 25, 2007). The loss-spreading justification is buttressed by the insight of law and economics that the cost of accidents is minimized by imposing the cost on "the 'cheapest cost avoider' or [the actor] who is in the best position to make the cost-benefit analysis between accident costs and accident avoidance costs and to act on that decision once it is made." *Beshada v. Johns-Manville Prods. Corp.*, 447 A.2d 539, 548 (N.J. 1982) (citing Guido Calabresi & Jon T. Hirschoff, *Toward a Test for Strict Liability in Torts*, 81 YALE L.J. 1055 (1972)). See generally Robert L. Rabin, *Reassessing Regulatory Compliance*, 88 GEO. L.J. 2049, 2071 (2000).

For a court or state legislature that held these views, a determination by the FDA that the cost of an additional warning outweighed the benefits would be beside the point, even if the lawmaker was confident the FDA was right. *Schneider Nat'l, Inc. v. Holland Hitch Co.*, 843 P.2d 561, 580 (Wyo. 1992) ("The risk allocation concept means that strict liability is not based on 'fault.' Instead of considering each actor's negligence or fault, the person most able to avoid accidents . . . is held liable for the cost of the accident.") (citations omitted). The court or legislature would still want to impose liability to spread losses from risks in a use of a drug that the FDA correctly determined were worth taking.[5] If the court or legislature thought there was a risk of regulatory error, then they would have an additional reason for imposing strict liability for it would increase their confidence that a company would warn of a risk if the benefits of the additional warning outweighed the cost.

In the United States, the trend in products liability law has been away from strict liability and towards negligence-based liability. This is particularly true in the area of pharmaceuticals with regards to

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[5] See *Wilson v. Piper Aircraft Corp.*, 577 P.2d 1322, 1333 (Or. 1978) (Linde, J., concurring) ("In a state where common law or legislation imposed absolute liability on a producer for certain kinds of harm in fact caused by his product, the fact that it had been thoroughly tested and approved for safety would be immaterial. But when liability is predicated on finding a design 'dangerously defective,' not 'duly safe,' or short of some similarly phrased standard of safety, then a careful comparison of that standard and the one attested to by the certificate becomes important.").

design defects.[6] See Jane Stapleton, *Liability for Drugs in the U.S. and EU: Rhetoric and Reality*, 26 REV. LITIG. 991 (2007).[7] But, as Professor Rabin has observed:

> More than a half century after *Escola [v. Coca Cola Bottling Co.*, 150 P.2d 436 (Cal. 1944)], the courts still have not reached a consensus on which rationale [compensation or regulation] should prevail. The divide is defined by those courts (and commentators) that would limit design defect and inadequate warning liability to some version of risk-benefit analysis, contrasted with those that would recognize a consumer expectations rationale, as well.

Rabin, 88 GEO. L.J. at 2071.

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[6] *Grundberg v. Upjohn Co.*, 813 P.2d 89 (Utah 1991), cites FDA regulation and the "unavoidably unsafe" nature of drugs as reasons not to impose strict liability. *Id.* at 90-92. This leaves to "courts to find liability under circumstances of inadequate warning, mismanufacture, improper marketing, or misinforming the FDA—avenues for which courts are better suited." *Id.* at 99.

[7] The gist of Professor Stapleton's argument is that the Europeans should learn from the U.S. experience and move away from a view that, at least rhetorically, treats liability for defective products, including drugs, as being strict. The leading European case on the character of liability is *A v. National Blood Authority*, [2001] 3 All ER 289 (Q.B.). It involves claims by Hemophiliacs given transfusions of blood infected by Hepatitis C. The court held the defendant liable, although the defendant was not negligent in failing to screen against Hepatitis C given the state of the art when the claims arose. The court interpreted the Product Liability Directive as intended to "achieve a higher and consistent level of consumer protection throughout the Community and render recovery of compensation easier, and uncomplicated by the need for proof of negligence." *Id.* at 310-11.

In particular, while it is now a minority position, some courts apply the "hindsight test" to determine whether a product was defective or, in the case of an FDA-approved drug, whether there was inadequate warning. The "hindsight test" assesses whether a product was defective—or, in the case of an FDA-approved drug, whether a warning was adequate—taking account of information that arose after a product was marketed. See *Sternhagen v. Dow Co.*, 935 P.2d 1139, 1147 (Mont. 1997); DAVID G. OWEN, PRODUCTS LIABILITY LAW § 8.7 (2005). A court that applies the hindsight test will hold a drug maker liable if risks that became apparent only in hindsight warranted an additional warning. The court would not be second-guessing the FDA's decision not to require such a warning for the agency does not have the benefit of hindsight.

Congress could decide that the interest in compensation is not sufficient to justify maintaining civil liability for failure to warn as a complement to FDA regulation. Congress has not done so here. To the contrary, recent legislation enacted in the wake of the Vioxx debacle expressly ratifies a regulatory requirement that a drug maker warn the public of risks the drug maker is aware of without waiting for action by the FDA.[8] It was well-known that this requirement is a linchpin of civil liability for it means FDA-approved warnings are not a ceiling on a drug maker's duty to warn.

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[8] See Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, § 901(a), 121 Stat. 823, 925-26 (codified at 21 U.S.C. § 355(*o*)(4)(I)) ("2007 FDA Amendments Act").

B. Regulating decisions outside the purview of the FDA's approval of a drug and its labeling.

Tort liability also has regulatory value. Sometimes it is a safeguard against regulatory failure. The FDA sometimes fails to protect the public from unreasonably dangerous drugs. The Vioxx experience is instructive:

> The picture that the Vioxx experience paints of FDA regulation of pharmaceutical products is one of an agency that has been very accommodating to the regulated industry in approving new and potentially highly beneficial drugs but not especially adept at detecting adverse side effects once these drugs are in use. At the same time, the pharmaceutical industry has been very aggressive in pushing potential "blockbuster" drugs through the approval process, and it has not been particularly forthcoming with the agency and the public when it comes upon warning signs of potential adverse outcomes. . . . Dr. David J. Graham . . . called the Vioxx episode "a profound regulatory failure," and he pessimistically concluded that "FDA as currently configured is incapable of protecting America against another Vioxx."

MCGARITY, *supra*, at 16.

Regulatory failure has many causes. The FDA is inadequately funded and staffed, drug makers may withhold relevant information, the FDA may be subject to regulatory capture, and drug makers may resist FDA action. But even if the agency were ade-

quately funded and staffed, and drug makers always worked hand-in-hand with the agency to ensure the safety and efficacy of drugs, failure-to-warn liability would still be warranted to encourage drug makers to warn about risks that are outside the purview of the FDA's decision when it approves a new drug and its labeling. Indeed, state courts and legislatures generally agree that regulatory approval of conduct should shield an actor from liability only with regard to risks that the regulator considered in approving the conduct. These reasons for maintaining failure-to-warn liability are independent of the quality of the FDA's analysis in approving a drug and its labeling.

1. Post-marketing risk information.

Approval of a new drug usually is based on limited clinical studies involving relatively small populations and relatively short time periods. "Once the drug enters the marketplace, risks that are relatively rare, that manifest themselves only after an extended period of time, or that affect vulnerable subpopulations, begin to emerge. These are often not risks foreseen by the drug's manufacturer or the FDA and, for that reason, are not addressed on the label." David A. Kessler & David C. Vladeck, *A Critical Examination of the FDA's Efforts to Preempt Failure-to-Warn Claims*, 96 GEO. L.J. 461, 466 (2008) (footnote omitted). "[F]ully one-half the adverse effects of newly marketed drugs are not discovered until after the drugs have been on the market for a while." MCGARITY, *supra*, at 237-38.

Historically, the FDA has expended vastly more resources evaluating new-drug applications than it does monitoring adverse events with existing drugs. See Kessler & Vladeck, 96 GEO. L.J. at 485. Doctor

Kessler and Professor Vladeck describe new tools and resources given to the FDA by the 2007 FDA Amendments Act to strengthen the agency's post-approval surveillance. *Id.* at 487-90.[9] But they conclude "it remains to be seen whether this increased surveillance will help the agency to recognize emerging safety problems more quickly." *Id.* at 490. Some problems are endemic. It is difficult for the FDA to assess adverse reaction reports when it "does not know how many people are using the drug or have information about their conditions." *Id.* And it takes time for the FDA to take effective action, particularly if the information the FDA has is inconclusive and a drug company puts up resistance.[10]

2. "Off-label use."

Drugs often are prescribed for "off-label use," meaning a use that has not been approved by the FDA.[11] It is estimated that "40-60% of prescriptions

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[9] These include express statutory authority to update labeling and to order new clinical trials, something the FDA had done in the past depending on the cooperation of drug makers.

[10] An FDA advisory panel recommended in early 2001 that the Vioxx label warn about the cardiovascular risk. This recommendation was based on a study that showed a correlation but Merck argued there was another cause. "Merck vigorously resisted this suggestion, arguing that the gastrointestinal benefits of Vioxx outweighed any cardiovascular risk. After fourteen months of negotiations, Merck and the agency compromised" on a diluted warning. The FDA acted quickly to take Vioxx off the market once it received the results of a more conclusive study in September 2004. See MCGARITY, *supra*, at 7-8.

[11] Fisch, the physician assistant who gave the harmful injection to respondent, disregarded the specified dosage, giving respondent a 50-mg double dose. For this reason, and because the

were written for off-label uses" and that "50% of cancer treatment drugs, 80-90% of drugs used to treat rare diseases, and 80% of drugs used in the pediatric field are prescribed off-label to patients." James O'Reilly & Amy Dalal, *Off-Label or Out of Bounds? Prescriber and Marketer Liability for Unapproved Uses of FDA-Approved Drugs*, 12 ANNALS HEALTH L. 295, 298 (2003). The fighting issue regarding FDA regulation of off-label uses has been whether and to what extent drug makers may promote off-label uses or educate physicians and the public about off-label uses. The FDA can warn the public and physicians about an unreasonably risky off-label use, and the FDA can ask a drug maker to stop marketing a drug when it learns of unreasonably dangerous off-label use. But this is after the fact, sometimes tragically so.

Fen-Phen is a case in point. Fenfluramine was combined with Phentermine to create a dietary suppressant that did not make people fall asleep. The popular press reported the results of a study published in 1992 that found subjects who used Fen-Phen lost 30 pounds on average in 9 months. It was off to the races. By 1996, physicians had written over 5 million prescriptions for Fen-Phen. The FDA never approved the combination. By the time the FDA asked Wyeth in 1997 to stop marketing the drug and a sister drug, Redux, it is estimated that 45,000 women had been harmed by taking one or the other. See Sue McGrath, *Only a Matter of Time: Lessons Unlearned at the Food and Drug Administration Keep Americans at Risk*, 60 FOOD & DRUG L.J. 603,

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label did not approve administration of Phenergan by IV-push, this case involves an "off-label use" of a drug.

613-16 (2005); ALICA MUNDY, DISPENSING WITH THE TRUTH (St. Martin's 2001).

3. Unexamined risks.

Petitioner argues (at 3-4, 11-16, 33, 44) that the jury was asked to override the FDA's determination that the potential benefits of intravenous injection of Phenergan outweighed the risks. This misstates the theory on which the case was litigated and what the FDA actually approved. The case was litigated on the theory that Wyeth was negligent in failing to warn against administration of Phenergan by IV-push.

The labeling of Phenergan neither approved nor warned against administration of Phenergan by IV-push. The labeling recommended "deep intramuscular injection." It warned of the hazard of IV administration and included the following instruction:

> When used intravenously, Phenergan Injection should be given in a concentration no greater than 25 mg per mL and at a rate not to exceed 25 mg per minute. When administering any irritant drug intravenously, it is usually preferable to inject it through the tubing of an intravenous infusion set that is known to be functioning satisfactorily.

JA 390. The label permits IV administration but mentions administration only by IV-drip. It neither expressly approves nor warns against administration by IV-push. As best we know, the FDA Advisory Committee and other relevant decision-makers never addressed the question whether the risk of admin-

istration of Phenergan by IV-push outweighed the benefits.

II. Preemption of state-law tort claims based on FDA regulation of a drug is unnecessary because the civil justice system defers to FDA expertise and protects drug makers from spurious claims.

Petitioner's policy arguments for preemption paint a picture of a world in which courts and juries freely disregard the FDA's judgments about drug efficacy and safety and about labeling and a world in which drug makers have little protection from spurious claims. Unsurprisingly, the real world looks nothing like this. State courts and legislatures are well aware that drugs that do great good also often come with great risk. And they respect the expertise of the FDA in deciding whether the benefits of a new drug outweigh the risks and in deciding what risks merit warning. What they have steadfastly refused to do is to immunize drug makers from failure-to-warn liability in the absence of a decision by the FDA that the specific risk in question did not warrant warning. Only one state legislature, Michigan, has taken this step. Petitioner asks this Court to do something that neither Congress, nor any other state legislature, nor any state court has thought prudent.

A. Tort law already defers to FDA's expertise in drug approval.

Over the last half century, tort law has evolved to a position in which courts largely cede to the FDA the authority to decide whether a new drug should be allowed on the market. Drug makers face a risk

of liability only for failing to warn of a drug's risks. Professor Owen summarizes the story:

> Whether and how prescription drugs in particular should be treated differently from other types of products has consumed more time and effort, and resulted in the gnashing of more teeth, than about any other particular issue in all of products liability law. In addition to featuring two prominent Restatement provisions—comment k to § 402A of the Restatement (Second) of Torts and § 6(c) of the Third Restatement, the drug design defect story wends through two of the most prominent cases in products liability law history—*Feldman v. Lederle Laboratories* and *Brown v. Superior Court*. The issue is complex, involving the learned intermediary doctrine, product category liability, state of the art, the battle for supremacy between the consumer expectations and risk utility tests of liability for design defectiveness, the never-ending struggle between negligence and strict liability, how design and warning defect notions fit together, federal preemption, and, at bottom, whether drugs in fact are different from other types of products, and whether they should be treated differently by products liability law.

OWEN, *supra*, at 549.

Professor Owen refers to an ongoing debate over when and how FDA-approved drugs should be shielded from products-liability claims in general and design-defect claims in particular. The issue emerges only after true strict liability (sometimes

referred to as absolute liability) is rejected in favor of negligence-based liability. Once this choice has been made, drugs are the paradigmatic example of what has come to be called an "unavoidably dangerous" product. This is a product—like a cigarette, a gun, or a knife—that must be dangerous if it is to perform its intended function. Products liability law generally is open to a claim that an unavoidably dangerous product should be designed more safely so it could serve its intended function with reduced risk.

Debate exists whether the law should permit a claim that a product was so dangerous, and of so little utility, that it is wrong to sell the product even if it can be made no safer while performing its intended function. While this is hotly contested terrain, there is a consensus that FDA-approved drugs should be shielded from both types of claims. It is thought that the FDA, better than a judge or jury, can decide whether the benefits of a new drug sufficiently outweigh the risk to justify placing the drug on the market, and whether the design of a drug can be tweaked to realize the benefits with reduced risk.

The debate has been over precisely when and how an FDA-approved drug should be shielded from a design-defect claim. Some courts have adopted a categorical rule precluding design-defect claims for FDA-approved drugs. This is the approach taken in *Brown v. Superior Court*, 751 P.2d 470 (Cal. 1988), and adopted in cases such as *Grundberg v. Upjohn Co.*, *supra*.[12] Other courts have taken a case-by-case

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[12] The *Grundberg* court summarized the justification:

> We find this extensive regulatory scheme capable of and appropriate for making the preliminary deter-

approach. Under this approach, the judge makes a preliminary determination whether a drug was defective as marketed or as designed. This is the approach taken in *Feldman v. Lederle Laboratories*, 479 A.2d 374 (N.J. 1984), and adopted and amplified in cases such as *Freeman v. Hoffman-La Roche, Inc.*, 618 N.W.2d 827 (Neb. 2000). This takes the issue out of the hands of the jury. The Restatement (Third) of Torts: Products Liability § 6(c) (1998) straddles the two approaches by supplying a rule that allows a claimant to proceed with a design-defect claim only if the foreseeable risks are so great, and foreseeable benefits so small, that no health-care professional would prescribe the drug "for any class of patients." Professor Owen observes that this "leaves a very small window for design defect claims for prescription drugs, a window so tiny that almost no drug claim could fit through it." OWEN, *supra*, at 557.

The upshot is that courts generally have ceded to the FDA the power to determine whether a new drug should be placed on the market as designed, so long as the drug maker is not aware of risks that it fails to disclose to the FDA. While ceding this ground, courts have retained failure-to-warn liability. Thus,

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> mination regarding whether a prescription drug's benefits outweigh its risks. The structured follow-up program imposed by law ensures that drugs are not placed on the market without continued monitoring for adverse consequences that would render the FDA's initial risk/benefit analysis invalid. Allowing individual courts and/or juries to continually reevaluate a drug's risks and benefits ignores the processes of this expert regulatory body and the other avenues of recovery available to plaintiffs.

813 P.2d at 97.

the Utah Supreme Court observed in *Grundberg*, 813 P.2d at 99: "Relying on the FDA's screening and surveillance standards enables courts to find liability under circumstances of inadequate warning, mismanufacture, improper marketing, or misinforming the FDA—avenues for which courts are better suited." This compromise facilitates getting new drugs on the market while using failure-to-warn liability to encourage dissemination of information about risks and so enable health-care professionals and the public to make informed decisions about drugs.

B. *Daubert* and the "learned intermediary doctrine."

Other judicially developed doctrines address specific policy arguments for preemption. One argument raises the specter of unsophisticated juries overriding the FDA based on junk science. Fifteen years ago, this Court, in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), interpreted Rule 702 of the Federal Rules of Evidence to empower trial judges to screen proffered expert scientific testimony to ensure that the testimony meets basic standards of scientific validity and reliability. Professor Owen observes: "Post-Daubert, the federal district courts, exercising their newly appointed 'gatekeeper' function, have scrutinized expert testimony more closely, often holding rigorous pre-trial 'Daubert hearings'—that are often outcome determinative—to determine the admissibility of proffered expert testimony." David G. Owen, *A Decade of Daubert*, 80 DENV. U. L. REV. 345, 362 (2002). While counts vary, it is estimated that a majority of states

now apply a similar standard. See OWEN, *supra*, at 376.

Another argument raises the specter of drug makers responding to the risk of liability by overwhelming consumers with warnings. This is avoided by the "learned intermediary" doctrine, which shields makers of prescription drugs from claims for failure to warn the public.[13] One codification of the doctrine states:

> [A prescription] drug is not defective due to inadequate warning or instruction if its manufacturer provides otherwise adequate warning and instruction to the physician or other legally authorized person who prescribes or dispenses that [prescription] drug for a claimant in question and if the federal food and drug administration has not provided that warning or instruction relative to that [prescription] drug is to be given directly to the ultimate user of it.

Ohio Rev. Code Ann. § 2307.76(C).

The learned intermediary doctrine obviates the need for preemption in one of the situations described by the FDA in the preamble to the 2006 labeling regulations.[14]

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[13] "The doctrine was first recognized in case law over 50 years ago, and since that time has been recognized and applied in nearly all jurisdictions in the country." Richard B. Goetz & Karen R. Growdon, *A Defense of the Learned Intermediary Doctrine*, 63 FOOD & DRUG L.J. 421, 421 (2008).

[14] The preamble states preemption is justified of "[c]laims that a drug sponsor breached an obligation to warn by failing to

C. The defense of regulatory compliance.

The ALI, state courts, and state legislatures have been grappling with the general question of whether and when civil courts and juries should defer to regulatory approval of allegedly negligent conduct in considering what has come to be called the defense of regulatory compliance. A broad consensus holds that regulatory approval of conduct should shield an actor from negligence liability only if the regulator considered the specific risk in question when it approved the conduct.

1. The evolving views of the ALI.

Over the last generation, the ALI has slowly moved towards a position that treats regulatory approval of allegedly negligent conduct as a basis for taking the issue of negligence away from the jury if the regulator considered the specific risk in question and decided that additional precautions were not worth taking.

While stating the traditional common-law position that statutes and regulations set a floor and not a ceiling on what is reasonable conduct, Restatement (Second) of Torts § 288C (1965) briefly acknowledges in Comment *a* the possibility that a court may treat a statute or regulation as determinative of what is reasonable conduct:

> [A] legislative or administrative minimum does not prevent a finding that a reasonable

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include in an advertisement any information the substance of which appears anywhere in the labeling, in those cases where a drug's sponsor has used Highlights consistently with FDA draft guidance regarding the 'brief summary' in direct-to-consumer advertising." 71 FED. REG. at 3936.

> man would have taken additional precautions where the situation is such as to call for them. . . . Where there are no such special circumstances, the minimum standard prescribed by the legislation or regulation may be accepted by the triers of fact, or by the court as a matter of law, as sufficient for the occasion . . . .

More recent Restatements expand on when a court may take the issue of the unreasonableness of conduct or the defectiveness of a product away from the jury because of legislative or regulatory approval of the conduct or product. Restatement (Third) of Torts: Products Liability § 4 (1998) explains in Comment *e*:

> Occasionally, after reviewing relevant circumstances, a court may properly conclude that a particular product safety standard set by statute or regulation adequately serves the objectives of tort law and therefore that the product that complies with the standard is not defective as a matter of law. Such a conclusion may be appropriate when the safety statute or regulation was promulgated recently, thus supplying currency to the standard therein established; when the specific standard addresses the very issue of product design or warning presented in the case before the court; and when the court is confident that the deliberative process by which the safety standard was established was full, fair, and thorough and reflected substantial expertise. Conversely, when the deliberative process that led to the safety

> standard with which the defendant's product complies was tainted by the supplying of false information to, or the withholding of necessary and valid information from, the agency that promulgated the standard or certified or approved the product, compliance with regulation is entitled to little or no weight.

Restatement (Third) of Torts: Liability for Physical Harm § 16 (Proposed Final Draft No. 1, 2005), after canvassing the situations in which compliance is not a defense, explains in Comment *f* when compliance may be a defense:

> *Statutory compliance as a limitation on liability.* While the Comments above explain the rule to the effect that compliance with statutes is usually no more than evidence of nonnegligence, the observations in the Comments suggest the rule's own limits. When the statute directly addresses the particular safety problem before the court, when the statutory scheme evidently seeks to identify all the precautions called for by the general negligence standards in § 3, and when the particular case involves no unusual circumstances, the court may conclude that the actor's compliance with the statute shows that the actor's conduct does not lack reasonable care. In reaching this conclusion, the court can take into account several factors, including the evident thoroughness of the statute and the desirability of a uniform liability standard that can simplify litigation and

> provide parties with appropriate guidance as to what precautions are expected of them.

ALI's Reporters' Study, *Enterprise Responsibility for Personal Injury* (1991), goes furthest towards endorsing a strong defense of regulatory compliance. After stating that, at a minimum, regulatory compliance should create a presumption of non-negligence and should shield an actor from punitive damages, the study goes on to recommend "making regulatory compliance a complete bar to tort liability once certain carefully-defined conditions have been satisfied respecting the regulation." *Id.* at 110. One condition is that "[t]he agency must have addressed the specific risk at issue in the case at hand, and must have made an explicit judgment about what type of legal controls are appropriate." *Id.* This condition is not satisfied in this case because the FDA never addressed the specific risk of administration of Phenergan by IV-push.

2. The defense of regulatory compliance in the courts.

Courts that have endorsed a defense of regulatory compliance limit the defense to cases in which the regulator considered the specific risk at issue in approving the challenged conduct. Justice Linde expressed the requirement pithily in a concurring opinion in *Wilson v. Piper Aircraft*, 577 P.2d at 1334-35:

> [I]t should be defendant's burden to show that a governmental agency has undertaken the responsibility of making substantially the same judgment that the court would otherwise be called on to make; and if so, it should

> then be plaintiff's burden to show that the responsible agency has not in fact made that judgment with respect to the particular "defect" at issue.

One leading case, *Ramirez v. Plough, Inc.*, 863 P.2d 167 (Cal.1993), involved a challenge to the labeling of a non-prescription drug. The plaintiff claimed it was negligent to market children's aspirin in California without a warning in Spanish of the risk of Reye's Syndrome. The California Supreme Court, affirming summary judgment for the defendant, found the FDA's decision not to require a Spanish-language warning conclusive on the issue of negligence: "[T]he FDA has concluded that despite the obvious advantages of multilingual package warnings, the associated problems and costs are such that at present warnings should be mandated only in English." *Id.* at 175.[15] In other words, court ruled for the defendant only because it concluded that the FDA had considered the relevant cost and benefits and decided the cost outweighed the benefits.

3. State legislation.

State legislatures have moved cautiously in making regulatory approval of conduct or a product a defense to a claim that the conduct was unreasonable or the product was defective. Regulatory approval of conduct or a product is generally relevant under

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[15] The bases for this conclusion were that the FDA required Spanish-language warnings on medicine sold in Puerto Rico and other territories where the predominant language was Spanish, 863 P.2d at 174, and the FDA had experimented with foreign-language package inserts but concluded that the cost outweighed the benefits, *id*. at 175.

state statutes only if the regulator specifically addressed the risk at issue in a case, and the approval creates only a presumption of non-negligence and non-defectiveness. Only Michigan has enacted a statute that shields a drug maker from liability for failure to warn about risks that the FDA did not consider in approving a drug and its labeling. Some states have enacted statutes that make FDA approval of a drug and labeling a general shield to liability for punitive damages, even with regards to risks not considered by the FDA.

a) Presumption of non-negligence and non-defectiveness.

A significant number of states have enacted statutes that provide for a rebuttable presumption of non-negligence and non-defectiveness if a regulator approves of conduct or a product. Some of the statutes are general while some apply only to FDA-approved drugs and labeling. See Ark. Code Ann. § 16-116-105; Colo. Rev. Stat. § 13-21-403; Fla. Stat. § 768.1256(1); Ind. Code § 34-20-5-1; Kan. Stat. Ann. § 60-3304(a) (enacting Model Uniform Product Liability Act § 108(A)[16] verbatim); Mich. Comp. Laws § 600.2946(4); N.J. Stat. Ann. § 2A:58C-4 (warning or instruction in compliance with regulatory approval under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act); N.D. Cent. Code

[16] The Model Uniform Product Liability Act was published by the Department of Commerce in 1979. See 44 FED. REG. 62,714 (Oct. 31, 1979).

§ 28-01.3-09; Tenn. Code Ann. § 29-28-104; Tex. Civ. Prac. & Rem. Code Ann. § 82.007.[17]

The rebuttable presumption is not toothless. *Schultz v. Ford Motor Co.*, 857 N.E.2d 977 (Ind. 2006), holds that the jury is told of the presumption. This invites the jury to defer to an agency if they are uncertain about whether a product was unreasonably dangerous. One court has gone further and endorsed instructing the jury that regulatory compliance is "strong and substantial evidence" of non-negligence and non-defectiveness. *Lorenz v. Celotex Corp.*, 896 F.2d 148, 149 (5th Cir. 1990) (Texas law).

The Vermont legislature has not enacted such legislation. Even if it had, the presumption would not have applied in this case because the FDA did not approve administration of Phenergan by IV-push. The presumption applies only if "the specific injury causing aspect of the product conformed to or was in compliance with the legislative or administrative regulatory standard." *Alvarado v. J.C. Penney Co.*, 735 F. Supp. 371, 373 (D. Kan. 1990) (quoting the comments to § 108 of the Model Uniform Product Liability Act). See also *Ehlis v. Shire Richwood, Inc.*, 233 F. Supp. 2d 1189, 1198-99 (D.N.D. 2002) (holding the presumption does not apply to an "off-label" use because the use was not approved by the FDA), *aff'd*, 367 F.3d 1013 (8th Cir. 2004).

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[17] Washington Revised Code § 7.72.050(1) merely provides that the trier of fact may consider evidence of compliance. This was to reverse a Washington case holding that the evidence was not admissible.

b) A shield against punitive damages.

Several states have statutes that shield drug manufacturers from punitive damages if a drug is manufactured and labeled in accordance with FDA approval. See Ariz. Rev. Stat. § 12-701; N.J. Stat. Ann. § 2A:58C-5(c); N.D. Cent. Code § 19-02.1-26(1); Ohio Rev. Code Ann. § 2307.80(C); Or. Rev. Stat. § 30.927; Utah Code Ann. § 78B-8-203. Typically, the shield is removed if a manufacturer knowingly withholds relevant information from the FDA.[18] Unlike the presumption, these statutes do not require that the FDA have considered the specific risk at issue. See, e.g., Ariz. Rev. Stat. § 12-701.

c) The Michigan statute.

In 1995, Michigan enacted a statute providing "a drug is not defective or unreasonably dangerous, and the manufacturer or seller is not liable, if the drug was approved for safety and efficacy by the United States food and drug administration, and the drug and its labeling were in compliance with the United States food and drug administration's approval at the time the drug left the control of the manufacturer or seller." Mich. Comp. Laws § 600.2946(5). The statute was upheld in *Taylor v. SmithKline Beecham Corp.*, 658 N.W.2d 127 (Mich. 2003).

The statute is unique in its breadth. It shields a drug maker from any liability based on a theory of negligence or products liability if a drug has been approved by the FDA. Unlike the defense of regula-

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[18] *McDarby v. Merck & Co.*, 949 A.2d 223, 271-76 (N.J. Super. Ct. App. Div. 2008), holds that this feature of the New Jersey statute is preempted under the logic of *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001).

tory compliance and the statutes creating a rebuttable presumption, the defense is not limited to claims involving risks actually addressed by the FDA. There is no exception for risks that appear post-marketing. And there is no exception for "off-label" uses the FDA never approved. The only exceptions are (i) if a company intentionally withholds information that it is required to submit under federal law that would have led the FDA not to approve the drug, or to withdraw approval, and (ii) if an FDA official is bribed.

III. This Court should leave it to Congress to craft appropriate preemption rules.

Preemption is not a simple either-or proposition. A narrow rule of preemption is similar to a strong form of the defense of regulatory compliance. It would make FDA approval of drug labeling determinative of non-negligence and non-defectiveness if the FDA considered the specific risk at issue in a case and concluded the labeling provided sufficient warning with respect to that risk. A state could still impose strict liability that did not require a finding that it was negligent to fail to give additional warning. In addition, liability would not be precluded if the FDA did not consider the specific risk at issue in approving the drug and labeling. Thus, a drug maker would be subject to liability if it had reason to know the labeling was deficient based on post-marketing risk information if the FDA had not yet considered whether the information justified additional warning. A drug maker would be liable for failure to warn about "off-label" uses not approved by the FDA. And a drug maker would be liable if the FDA did not consider the specific risk at issue (as in this case,

because the FDA did not approve administration of Phenergan by IV-push). Additional exceptions might also be made for cases in which a drug maker withholds relevant risk information to the FDA or unduly influences the FDA's decision.

A broad form of preemption would be similar to the Michigan statute. It would shield a drug maker from all claims regarding an FDA-approved drug and labeling so long as the drug maker complied with the FDA's orders. A claim would be precluded even if the FDA did not consider, and could not have considered, the relevant risk when approving labeling. While the Michigan statute makes exception for cases in which a drug maker withholds crucial risk information, or in which a drug maker bribes an FDA official, one could dispense even with these exceptions.

There are intermediate possibilities. A narrow form of preemption could be supplemented by a rule precluding a state from imposing strict liability. And drug makers could be shielded from punitive damages.

Ideally, Congress or, in the absence of congressional action, state legislatures should choose among alternative preemption rules because the choice turns on fundamental questions of morality and policy on which there is deep disagreement, as well as contestable empirical assumptions. The choice only obliquely turns on views of the relative strengths and weaknesses of the FDA and courts in regulating drug warnings.

In particular, Congress can best weigh the interests in corrective justice and compensation, which

justify civil liability, against the concerns for litigation cost and error, and the interest in national uniformity, which justify preemption. The political branches are also in the best position to give due weight to the fundamental federalism concerns that would be raised by any effort to preempt such basic and well-established state-law tort principles. Finally, institutional concerns point to Congress. Congress can legislate rules that resolve predictable boundary-drawing problems. This Court can resolve only the particular case before it. It would require a series of cases to define even the most general contours of preemption.

A possible alternative might be to have the FDA rule on a case-by-case basis, as it approves a particular drug and labeling, whether, and the extent to which, preemption of civil liability is warranted. The agency has done this in the past by rulemaking in specific situations when it deemed it warranted.[19]

Congress should also decide whether a preemption rule applies retroactively or prospectively. Until the FDA's recent change of position, it was generally assumed that FDA approval of a drug and labeling did not shield a drug maker from failure-to-warn liability, particularly for risks that the FDA did not consider in approving the labeling. FDA officials may well have rested easier in approving a drug and its labeling because they knew they were not solely responsible for protecting the public from unreasonably dangerous drugs. Certainly they would not have thought the legal system expected them to be

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[19] Examples are collected at 71 FED. REG. at 3935.

omniscient and to anticipate post-marketing risks and off-label uses.

CONCLUSION

The judgment of the Supreme Court of Vermont should be affirmed.

Respectfully submitted,

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APPENDIX

More detailed biographical information about each of the *amici* is as follows:

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Professor Gergen currently holds the Fondren Foundation Centennial Chair for Faculty Excellence at the University of Texas School of Law, where he has been a member of the faculty since 1986. This fall, he will join the faculty of Boalt Hall School of Law, University of California at Berkeley. He has taught and written on the entire spectrum of the law of obligations: contracts, torts, and restitution. He was the reporter for *Restatement (Third) of Torts: Economic Torts and Related Wrongs*.

Michael D. Green

Professor Green holds the Bess and Walter Williams Distinguished Chair at the Wake Forest School of Law. For the last 28 years, he has regularly taught and written about torts and a variety of advanced torts subjects. He serves as a co-reporter for the *Restatement (Third) of Torts: Liability for Physical Harm*.